HOUSE BILL No. 1382

DIGEST OF INTRODUCED BILL

Citations Affected: IC 5-10-8-15; IC 12-15-5-9; IC 27-8-25; IC 27-13-7-20.

Synopsis: Insurance coverage for clinical trials. Requires coverage for certain services related to clinical trials under a state employee health plan, the state Medicaid program, a policy of accident and sickness insurance, and a health maintenance organization contract.

Effective: July 1, 2009.

Welch, Brown C, Brown T

January 13, 2009, read first time and referred to Committee on Public Health.





First Regular Session 116th General Assembly (2009)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in this style type, and deletions will appear in this style type.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in this style type. Also, the word NEW will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in this style type or this style type reconciles conflicts between statutes enacted by the 2008 Regular Session of the General Assembly.

HOUSE BILL No. 1382

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

the use of a particular drug or device in a particular manner.	
1, 2009]: Sec. 15. (a) As used in this section, "care method" means	
AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY	V
SECTION 1. IC 5-10-8-15 IS ADDED TO THE INDIANA CODE	

- (b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:
 - (1) that is conducted:
 - (A) using a particular care method to prevent, diagnose, or treat a cancer or another serious or life threatening disease for which:
 - (i) there is no clearly superior, noninvestigational alternative care method; and
 - (ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;
 - (B) in a facility where personnel providing the care method



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1	to be followed in the research study have:	
2	(i) received training in providing the care method;	
3	(ii) expertise in providing the type of care required for	
4	the research study; and	
5	(iii) experience providing the type of care required for	
6	the research study to a sufficient volume of patients to	
7	maintain expertise; and	
8	(C) to scientifically determine the best care method to	
9	prevent, diagnose, or treat the cancer or other serious or	_
0	life threatening disease; and	4
.1	(2) that is:	
2	(A) exempt from the federal Food and Drug	
.3	Administration's investigational new drug or device	
4	application requirement as provided under 21 CFR 312 or	
.5	21 CFR 812; or	
6	(B) approved or funded by one (1) of the following:	
7	(i) A National Institutes of Health institute.	
.8	(ii) A cooperative group of research facilities that has an	
9	established peer review program that is approved by a	
20	National Institutes of Health institute or center.	
2.1	(iii) The federal Food and Drug Administration.	_
22	(iv) The United States Department of Veterans Affairs.	
23	(v) The United States Department of Defense.	
24	(vi) The institutional review board of an institution	
2.5	located in Indiana that has a multiple project assurance	
26	contract approved by the National Institutes of Health	_
27	Office for Protection from Research Risks as provided in	
28	45 CFR 46.103.	
29	(vii) A research entity that meets eligibility criteria for a	
30	support grant from a National Institutes of Health center.	
51 52	(c) As used in this section, "covered individual" means an	
3	individual entitled to coverage under a state employee health plan.	
3 34	(d) As used in this section, "routine care cost" means the cost of	
55	medically necessary services related to the care method that is	
66	under evaluation in a clinical trial. The term does not include the	
57	following:	
8	(1) The drug or device that is under evaluation in a clinical	
9	trial.	
10	(2) Items or services that are:	
1	(A) provided solely for data collection and analysis and not	
12	in the direct clinical management of an individual enrolled	
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1	in a clinical trial;	
2	(B) customarily provided at no cost by a research sponsor	
3	to an individual enrolled in a clinical trial; or	
4	(C) provided solely to determine eligibility of an individual	
5	for participation in a clinical trial.	
6	(e) As used in this section, "state employee health plan" means	
7	one (1) of the following:	
8	(1) A self-insurance program established under section 7(b) of	
9	this chapter to provide group health coverage.	
10	(2) A contract with a prepaid health care delivery plan that is	
11	entered into or renewed under section 7(c) of this chapter.	
12	(f) A state employee health plan that provides coverage for basic	
13	health care services shall provide coverage for routine care costs	
14	related to a clinical trial for a covered individual participating in	
15	the clinical trial.	_
16	SECTION 2. IC 12-15-5-9 IS ADDED TO THE INDIANA CODE	
17	AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY	
18	1, 2009]: Sec. 9. (a) As used in this section, "care method" means	
19	the use of a particular drug or device in a particular manner.	
20	(b) As used in this section, "clinical trial" means a Phase I, II,	
21	III, or IV research study:	
22	(1) that is conducted:	
23	(A) using a particular care method to prevent, diagnose, or	
24	treat a cancer or another serious or life threatening disease	_
25	for which:	
26	(i) there is no clearly superior, noninvestigational	
27	alternative care method; and	
28	(ii) available clinical or preclinical data provides a	T T
29	reasonable basis from which to believe that the care	
30	method used in the research study is at least as effective	
31	as any noninvestigational alternative care method;	
32	(B) in a facility where personnel providing the care method	
33	to be followed in the research study have:	
34	(i) received training in providing the care method;	
35	(ii) expertise in providing the type of care required for	
36	the research study; and	
37	(iii) experience providing the type of care required for	
38	the research study to a sufficient volume of patients to	
39	maintain expertise; and	
40	(C) to scientifically determine the best care method to	
41	prevent, diagnose, or treat the cancer or other serious or	
42	life threatening disease; and	



1	(2) that is:	
2	(A) exempt from the federal Food and Drug	
3	Administration's investigational new drug or device	
4	application requirement as provided under 21 CFR 312 or	
5	21 CFR 812; or	
6	(B) approved or funded by one (1) of the following:	
7	(i) A National Institutes of Health institute.	
8	(ii) A cooperative group of research facilities that has an	
9	established peer review program that is approved by a	
10	National Institutes of Health institute or center.	
11	(iii) The federal Food and Drug Administration.	
12	(iv) The United States Department of Veterans Affairs.	
13	(v) The United States Department of Defense.	
14	(vi) The institutional review board of an institution	
15	located in Indiana that has a multiple project assurance	
16	contract approved by the National Institutes of Health	
17	Office for Protection from Research Risks as provided in	
18	45 CFR 46.103.	
19	(vii) A research entity that meets eligibility criteria for a	
20	support grant from a National Institutes of Health	
21	center.	
22	(c) As used in this section, "routine care cost" means the cost of	
23	medically necessary services related to the care method that is	
24	under evaluation in a clinical trial. The term does not include the	
25	following:	
26	(1) The drug or device that is under evaluation in a clinical	
27	trial.	
28	(2) Items or services that are:	V
29	(A) provided solely for data collection and analysis and not	
30	in the direct clinical management of an individual enrolled	
31	in a clinical trial;	
32	(B) customarily provided at no cost by a research sponsor	
33	to an individual enrolled in a clinical trial; or	
34	(C) provided solely to determine eligibility of an individual	
35	for participation in a clinical trial.	
36	(d) The Medicaid program shall provide coverage for routine	
37	care costs related to a clinical trial for a recipient participating in	
38	the clinical trial.	
39	(e) The office shall apply to amend the state Medicaid plan if the	
40	office determines that an amendment is necessary to carry out this	
41	section.	
42	SECTION 3. IC 27-8-25 IS ADDED TO THE INDIANA CODE AS	



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1	A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY	
2	1, 2009]:	
3	Chapter 25. Coverage for Care Related to Clinical Trials	
4	Sec. 1. As used in this chapter, "care method" means the use of	
5	a particular drug or device in a particular manner.	
6	Sec. 2. As used in this chapter, "clinical trial" means a Phase I,	
7	II, III, or IV research study:	
8	(1) that is conducted:	
9	(A) using a particular care method to prevent, diagnose, or	
10	treat a cancer or another serious or life threatening disease	
11	for which:	
12	(i) there is no clearly superior, noninvestigational	
13	alternative care method; and	
14	(ii) available clinical or preclinical data provides a	
15	reasonable basis from which to believe that the care	
16	method used in the research study is at least as effective	
17	as any noninvestigational alternative care method;	
18	(B) in a facility where personnel providing the care method	
19	to be followed in the research study have:	
20	(i) received training in providing the care method;	
21	(ii) expertise in providing the type of care required for	
22	the research study; and	
23	(iii) experience providing the type of care required for	
24	the research study to a sufficient volume of patients to	
25	maintain expertise; and	
26	(C) to scientifically determine the best care method to	
27	prevent, diagnose, or treat the cancer or other serious or	,
28	life threatening disease; and	
29	(2) that is:	
30	(A) exempt from the federal Food and Drug	
31	Administration's investigational new drug or device	
32	application requirement as provided under 21 CFR 312 or	
33	21 CFR 812; or	
34	(B) approved or funded by one (1) of the following:	
35	(i) A National Institutes of Health institute.	
36	(ii) A cooperative group of research facilities that has an	
37	established peer review program that is approved by a	
38	National Institutes of Health institute or center.	
39	(iii) The federal Food and Drug Administration.	
40	(iv) The United States Department of Veterans Affairs.	
41	(v) The United States Department of Defense.	
42	(vi) The institutional review board of an institution	



1	located in Indiana that has a multiple project assurance	
2	contract approved by the National Institutes of Health	
3	Office for Protection from Research Risks as provided in	
4	45 CFR 46.103.	
5	(vii) A research entity that meets eligibility criteria for a	
6	support grant from a National Institutes of Health	
7	center.	
8	Sec. 3. As used in this chapter, "covered individual" means an	
9	individual entitled to coverage under a policy of accident and	
0	sickness insurance.	
.1	Sec. 4. As used in this chapter, "policy of accident and sickness	
2	insurance" has the meaning set forth in IC 27-8-5-1. The term does	
3	not include the following:	
4	(1) Accident only, credit, dental, vision, Medicare, Medicare	
.5	supplement, long term care, or disability income insurance.	
6	(2) Coverage issued as a supplement to liability insurance.	
7	(3) Automobile medical payment insurance.	
. 8	(4) A specified disease policy.	
9	(5) A limited benefit health insurance policy.	
20	(6) A short term insurance plan that:	
21	(A) may not be renewed; and	
22	(B) has a duration of not more than six (6) months.	
23	(7) A policy that provides a stipulated daily, weekly, or	
24	monthly payment to an insured during hospital confinement,	
2.5	without regard to the actual expense of the confinement.	
26	(8) Worker's compensation or similar insurance.	
27	(9) A student health insurance policy.	
28	Sec. 5. As used in this chapter, "routine care cost" means the	V
29	cost of medically necessary services related to the care method that	
0	is under evaluation in a clinical trial. The term does not include the	
31	following:	
32	(1) The drug or device that is under evaluation in a clinical	
3	trial.	
34	(2) Items or services that are:	
55	(A) provided solely for data collection and analysis and not	
66	in the direct clinical management of an individual enrolled	
57	in a clinical trial;	
8	(B) customarily provided at no cost by a research sponsor	
19	to an individual enrolled in a clinical trial; or	
10	(C) provided solely to determine eligibility of an individual	
1	for participation in a clinical trial.	
12	Sec. 6. A policy of accident and sickness insurance shall provide	



1	coverage for routine care costs related to a clinical trial for a	
2	covered individual participating in the clinical trial.	
3	SECTION 4. IC 27-13-7-20 IS ADDED TO THE INDIANA CODE	
4	AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY	
5	1, 2009]: Sec. 20. (a) As used in this section, "care method" means	
6	the use of a particular drug or device in a particular manner.	
7	(b) As used in this section, "clinical trial" means a Phase I, II,	
8	III, or IV research study:	
9	(1) that is conducted:	
10	(A) using a particular care method to prevent, diagnose, or	
11	treat a cancer or another serious or life threatening disease	
12	for which:	
13	(i) there is no clearly superior, noninvestigational	
14	alternative care method; and	
15	(ii) available clinical or preclinical data provides a	_
16	reasonable basis from which to believe that the care	
17	method used in the research study is at least as effective	
18	as any noninvestigational alternative care method;	
19	(B) in a facility where personnel providing the care method	
20	to be followed in the research study have:	
21	(i) received training in providing the care method;	
22	(ii) expertise in providing the type of care required for	
23	the research study; and	
24	(iii) experience providing the type of care required for	-
25	the research study to a sufficient volume of patients to	
26	maintain expertise; and	
27	(C) to scientifically determine the best care method to	
28	prevent, diagnose, or treat the cancer or other serious or	V
29	life threatening disease; and	
30	(2) that is:	
31	(A) exempt from the federal Food and Drug	
32	Administration's investigational new drug or device	
33	application requirement as provided under 21 CFR 312 or	
34	21 CFR 812; or	
35	(B) approved or funded by one (1) of the following:	
36	(i) A National Institutes of Health institute.	
37	(ii) A cooperative group of research facilities that has an	
38	established peer review program that is approved by a	
39	National Institutes of Health institute or center.	
40 4.1	(iii) The federal Food and Drug Administration.	
41 42	(iv) The United States Department of Veterans Affairs.	
42	(v) The United States Department of Defense.	



1	(vi) The institutional review board of an institution	
2	located in Indiana that has a multiple project assurance	
3	contract approved by the National Institutes of Health	
4	Office for Protection from Research Risks as provided in	
5	45 CFR 46.103.	
6	(vii) A research entity that meets eligibility criteria for a	
7	support grant from a National Institutes of Health	
8	center.	
9	(c) As used in this section, "routine care cost" means the cost of	
10	medically necessary services related to the care method that is	
11	under evaluation in a clinical trial. The term does not include the	
12	following:	
13	(1) The drug or device that is under evaluation in a clinical	
14	trial.	
15	(2) Items or services that are:	
16	(A) provided solely for data collection and analysis and not	
17	in the direct clinical management of an individual enrolled	
18	in a clinical trial;	
19	(B) customarily provided at no cost by a research sponsor	
20	to an individual enrolled in a clinical trial; or	
21	(C) provided solely to determine eligibility of an individual	
22	for participation in a clinical trial.	
23	(d) An individual contract or a group contract that provides	
24	coverage for basic health care services shall provide coverage for	
25	routine care costs related to a clinical trial for an enrollee	
26	participating in the clinical trial.	
27	SECTION 5. [EFFECTIVE JULY 1, 2009] (a) IC 5-10-8-15, as	
28	added by this act, applies to a state employee health plan that is	V
29	established, entered into, issued, delivered, amended, or renewed	
30	after June 30, 2009.	
31	(b) IC 12-15-5-9, as added by this act, applies to a Medicaid risk	
32	based managed care contract that is entered into, delivered,	
33	amended, or renewed after June 30, 2009.	
34	(c) IC 27-8-25, as added by this act, applies to a policy of	
35	accident and sickness insurance that is issued, delivered, amended,	
36	or renewed after June 30, 2009.	
37	(d) IC 27-13-7-20, as added by this act, applies to an individual	
38	contract or a group contract that is entered into, delivered,	
39	amended, or renewed after June 30, 2009.	
40	(e) This SECTION expires July 1, 2014.	

